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EXAMINER	
HUYNH, PHUONG N	
ART UNIT	**PAPER NUMBER**
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/658,491	NASH ET AL.	
	Examiner	Art Unit	
	Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) *13-17 and 30-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12, 18-29, and 36-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/25/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-42 are pending.

2. Applicant's election of Group 1, Claims 1-12, 18-29, and 36-42 drawn to a method of production of a specific microbial adherence inhibitor for administration to food animals to control the incidence of acidosis in food animal, the method wherein the colony forming immunogen is a specific immunogen wherein the immunogen is SB antigen from Streptococcus bovis, a microbial adherence inhibitor produced by said method, filed 11/14/05, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 13-17, and 30-35 are withdrawn from further consideration by the examiner, 37 C.F.R. 1.142(b) as being drawn to non-elected inventions.

4. Claims 1-12, 18-29, and 36-42, drawn to a method of production of a specific microbial adherence inhibitor for administration to food animals to control the incidence of acidosis in food animal, the method wherein the colony forming immunogen is a specific immunogen wherein the immunogen is SB antigen from Streptococcus bovis, a microbial adherence inhibitor produced by said method, are being acted upon in this Office Action.

5. Claims 2, 4, 19, and 37 are objected to as the claims encompass non-elected embodiments.

6. The disclosure is objected to because of the following informality: the unit for "250μ" on page 20, last line is missing. It is not clear if it is 250μl or 250μg.

7. The abstract of the disclosure is objected to because it is too long. Correction is required. See MPEP § 608.01(b). Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet **within the range of 50 to 150 words**. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the

printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

8. Claim 8 is objected to because "SN antigen" in claim 8, line 9 should have been "SB antigen".

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1, 3, 5-7, 18, 36 and 40-42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling only for (1) a method of producing a microbial adherence inhibitor for administration to food animals to control the incidence of acidosis in food animal by preventing the adherence of colony-forming lactic acid producing *streptococcus bovis* in the rumen or intestinal tracts of said food animals, which method comprises: a. inoculating female birds, in or about to reach their egg laying age, with *streptococcus bovis*; b. allowing a period of time sufficient to permit the production in the bird of antibody to *streptococcus bovis*, c. harvesting the eggs laid by the birds; and separating the antibody-containing contents of said eggs from the shells, d. drying the separated antibody-containing contents of said eggs alone or onto feed carrier wherein the carrier is selected from the group consisting of soybean hulls, rice hulls, corn, cottonseed hulls, (2) the said method of producing a microbial adherence inhibitor wherein the method step includes mixing the antibody-containing contents of the eggs with a liquid carrier wherein the liquid carrier is selected from the group consisting of liquid molasses and PBS, **does not** reasonably provide enablement for a method of producing any microbial adherence inhibitor for administration to any food animals to control the incidence of acidosis in food animals by preventing the adherence of any "colony-forming lactic acid producing immunogen" in the rumen or intestinal tracts of said food animals, which method comprises: a. inoculating female birds, in or about to reach their egg laying age, with any lactic acid producing immunogen as set forth in claims 1, 3, 5-7, 18 or a method for reducing or eliminating the incidence of lactic acid in any food animals caused by the presence of any lactic acid forming and liver abscess forming immunogens in the animal by inoculating female birds, in or about to reach their egg laying age, with any lactic acid producing immunogens as set forth in claims 36 and 40. The specification

does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in **scope** with these claims.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention. The specification disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without an undue amount of experimentation.

The specification discloses only three lactic acid producing bacteria *Streptococcus bovis, Lactobacillus spp* and *Fusobacterium necrophorum* to be used as an immunogen for a method of producing egg antibody microbial inhibitor for administration to food animals to control the incidence of acidosis in food animal. The method comprises inoculating female birds, in or about to reach their egg laying age, with a lactic acid producing immunogen *Streptococcus bovis* or SB antigen from *Streptococcus bovis* produced by the method disclosed on page 17, allowing a period of time to permit the production in the birds and eggs laid by the birds of antibody specific to *Streptococcus bovis*, harvesting the eggs laid by the birds, and separating the antibody-containing contents of said harvested eggs from the eggshells, drying the total egg antibody-containing contents of the harvested eggs from the eggshells alone or onto feed carrier such as dry soy or rice husks, distributing the resulting egg mixture antibody product uniformly through animal feed or water and supplying the resulting antibody-containing animal feed or water to food animal to substantially prevent the adherence of *Streptococcus bovis* to the rumen or intestinal tracts of the animals.

The specification does not teach how to make much less how to use any microbial adherence inhibitor other than the ones mentioned above. There is insufficient guidance as to the binding specificity of the egg antibody microbial adherence inhibitor in the claimed method. There is insufficient guidance as to the specific "lactic acid producing immunogen" other than the specific *Streptococcus bovis, Lactobacillus spp* and *Fusobacterium necrophorum* to be inoculating the female birds for a method of producing egg antibody microbial adherence inhibitor. The terms "lactic acid producing immunogen", or "colony forming lactic acid producing immunogen" in the claimed method encompasses any lactic acid producing bacteria.

However, not all "lactic acid producing immunogen" colonize the intestinal tracts of all food animals and responsible for the incidence of acidosis. Further, the specification does not teach the structure of the "SB antigen" from *streptococcus bovis* without the amino acid sequence. The "SB antigen" from *streptococcus bovis* as disclosed on page 17 is whole cell bacteria grown in the Brain Heart Infusion (BHI) medium. The whole bacteria *streptococcus bovis* are inactivated with heat or 0.8% formaldehyde and then used as an immunogen to inoculate the female birds for making egg antibody.

Stryer *et al* teach that a protein is highly dependent on the overall structure of the protein itself and that the primary amino acid sequence determines the conformational of the protein (See enclosed appropriate pages).

Given the unlimited number of undisclosed immunogens, there is insufficient in vivo working examples demonstrating that microbial adherence inhibitor such as any avian antibody produced by inoculating the birds with any undisclosed immunogen is effective for inhibiting the ability of any organism to adhere to the rumen of or intestinal tracts of animals to reduce the ability of any bacteria from adhere to the rumen or intestinal tracts of all food animals.

It is well known that not all immunogen or antigen on any given microorganism plays a role in adherence and colonizing the rumen or intestinal tract of any animal. Even if the immunogen is known, the antibody generated from the specific immunogen can only be specific to that immunized immunogen. For example, immunizing an egg-laying hen with bacteria *streptococcus bovis* can generate antibody only specific to *streptococcus bovis* and under no circumstance can the hen generate antibody to the other lactic acid producing bacteria such as *Fusobacterium necrophorum*.

Kuby *et al* teach that antibody epitopes (B cell epitopes) are not linear and are comprised of complex three-dimensional array of scattered residues which will fold into specific conformation that contribute to binding (See Kuby 1994, page 94, in particular). Immunization with a peptide fragment derived from a full-length polypeptide may result in **antibody specificity** that differs from the antibody specificity directed against the native full-length polypeptide.

Given the unlimited number of undisclosed lactic acid producing immunogen, it is unpredictable which egg antibody microbial adherence inhibitor produced by immunizing a hen with any undisclosed lactic acid immunogen will have the same antibody specificity as the egg antibody that produced by inoculating the bird with *streptococcus* bovis, in turn, would be useful for any purpose.

For these reasons, it would require undue experimentation of one skilled in the art to practice the claimed invention. See page 1338, footnote 7 of Ex parte Aggarwal, 23 USPQ2d 1334 (PTO Bd. Pat App. & Inter. 1992).

In re wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988), the decision of the court indicates that the more unpredictable the area is, the more specific enablement is necessary. In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take an undue amount of experimentation for one skilled in the art to practice the claimed invention.

11. Claims 1, 3, 5-7, 18, 36 and 40-42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The specification does not reasonably provide a **written description** of *any* "lactic acid producing immunogen" for the claimed methods.

The specification discloses only three lactic acid producing bacteria *Streptococcus bovis, Lactobacillus spp* and *Fusobacterium necrophorum* to be used as an immunogen for a method of producing egg antibody microbial inhibitor for administration to food animals to control the incidence of acidosis in food animal. The method comprises inoculating female birds, in or about to reach their egg laying age, with a lactic acid producing immunogen *Streptococcus bovis* or SB antigen from *Streptococcus bovis* produced by the method disclosed on page 17, allowing a period of time to permit the production in the birds and eggs laid by the birds of antibody specific to *Streptococcus bovis*, harvesting the eggs laid by the birds, and separating the antibody-containing contents of said harvested eggs from the eggshells, drying the total egg antibody-containing contents of the harvested eggs from the eggshells alone or onto feed carrier such as dry soy or rice husks, distributing the resulting egg mixture antibody product uniformly through animal feed or water and supplying the resulting antibody-containing animal feed or water to food animal to substantially prevent the adherence of *Streptococcus bovis* to the rumen or intestinal tracts of the animals.

Other the specific lactic acid producing bacteria for use as an immunogen for the production of the specific egg antibody microbial adherence inhibitor that inhibit the adherence of

the specific *Streptococcus bovis* in the rumen or intestinal tracts of food animals, there is inadequate written description about the other lactic acid producing immunogens in all food animals for the claimed methods.

Further, the specification does not disclose the structure of the "SB antigen" from *streptococcus bovis* without the amino acid sequence. The "SB antigen" from *streptococcus bovis* as disclosed on page 17 is whole cell bacteria grown in the Brain Heart Infusion (BHI) medium. The whole bacteria *streptococcus bovis* are inactivated with heat or 0.8% formaldehyde and used as immunogen. Inoculating any female bird with the specific bacteria can only produce microbial inhibitor such as avian antibody to the specific bacteria. Given the indefinite number of undisclosed "colony-forming lactic acid producing immunogens", the claimed methods of using the undisclosed immunogens are not adequately described.

Since the specification discloses only a microbial inhibitor produced by inoculating female bird with *streptococcus bovis*, *Lactobacillus spp* or *Fusobacterium necrophorum*, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus. *See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.*

Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

13. Claims 7, 12 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The "liquid extender" in claims 7, 12 and 29 is ambiguous and indefinite because the specification does not define the term "liquid extender". One of ordinary skill in the art cannot appraise the metes and bounds of the claimed invention.

14. The filing date of the instant claims is deemed to be the filing date of the instant application 10/658,491, as the parent applications 10/038,260 filed 1/7/02, 09/616,843 filed 07/14/00 and

provisional applications 60/201,268 filed 5/2/00 and 60/143,985 filed 7/15/99 do not support the claimed limitations of a method of production of a microbial adherence inhibitor for administration of food animal to control the *incidence of acidosis* in food animal by inoculating female birds with colony forming *lactic acid producing immunogen*, and said colony forming immunogen is from the class of *Streptococcus bovis* and liquid extender such as liquid molasses and PBS of the instant application.

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

16. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

17. Claims 1-4 and 18-19 are rejected under 35 U.S.C. 102(e) as being anticipated by US Pat No 6,419,926 B2 (filed April 8, 1998; PTO 892).

The '926 patent teaches an egg antibody microbial adherence inhibitor to control the incidence of acidosis such as ulcer caused by lactic acid producing immunogen or bacteria such as *Lactobacillus salivaious, enterococcuses, yeasts, and bacillus* (see col. 6, lines 46-54, in particular). The reference microbial inhibitor is provides as a food additive (see col. 5, lines 14-15, in particular). A product is a product, irrespective of its intended use such as "for administration to food animal" as recited in claim 18. The reference egg antibody microbial adherence inhibitor is produced by inoculating female birds such as hens with bacteria such as *Lactobacillus salivaious, enterococcuses, yeasts, or bacillus* (see col. 5, lines 52-67, in particular), allowing a period of time such as six weeks sufficient to permit the production in the birds of antibody to the reference lactic acid producing immunogen (see col. 5, lines 55, col. 7,

lines 4-9, col. 8, lines 56-67, in particular), harvesting the eggs laid by the bird (see col. 9, lines 1-3, in particular), separating the antibody-containing contents of said eggs from the shells without fractionation (see col. 6, lines 25-27, in particular). The reference method of making microbial adherence inhibitor includes drying the whole egg antibody containing contents without fractionation by conventional technique such as spray drying or lyophilizing (see col. 6, lines 25-33, in particular). The reference egg antibody microbial inhibitor can prevent the adhesion of the reference lactic acid producing bacteria from adhering to the digestive tracks of mammals (see col. 6, lines 38-45, in particular). The reference egg antibody can be used as a solution or an emulsion or as a solid such as powder or granules by drying or mixed in a pharmaceutical acceptable carrier if desired (see col. 6, lines 65-67 bridging col. 7, lines 1-25, in particular). The reference egg antibody that binds to lactic acid producing bacteria inherently also prevents the adherence of *Lactobacillus salivaious* in the rumen or intestinal tracts of food animals. Thus, the reference teachings anticipate the claimed invention.

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 103(a) that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. Claims 1-4, 8-9, 18-21 and 25-26, 36-37, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (Jan 1992; PTO 1449) in view of US Pat No 6,287,555 B1 (filed May 13, 1998; PTO 892).

The '895 patent teaches a method of producing a microbial adherence inhibitor such as egg antibody that binds specifically to colony-forming immunogen such as *E coli* that inhibits the microbacteria from adhering to the intestinal track of livestock. The reference microbial adherence inhibitor egg antibody is produced by the method of inoculating an egg laying female birds such as the hen in their egg laying age with an immunogen such as bacterium *E coli*, wherein the reference E coli is a colony-forming bacteria (See column 5, lines 29-30, in particular), allowing a period of time such as a few weeks after inoculation sufficient to permit the production of bird antibody that binds to the targeted immunogen such as *E Coli* (See column 5, lines 47-60, column 6, 10-18, in particular). The reference method includes harvesting the

eggs laid by the hens (See column 6, line 1, in particular), separating the antibody containing contents of both the yolk and albumin from the shells (See column 6, lines 19-20, in particular), drying the separated egg antibody from the shells by spray drying or lyophilizing to form powder product (See column 6, line 24-25, in particular). The dried egg antibody is used as an additive to food for animal or in a liquid carrier such as milk to livestock to prevent adherence of the targeted immunogen in the intestinal tract of the animal (See column 9, line 42-46, column 10, line 30, column 5 lines 29 bridging column 6, lines 1-49, column 9, lines 43-57, column 10, line 29-31, in particular). The '895 patent teaches antibody containing egg powder from eggs of immunized hen against the bacterium which induces the disease is useful as additives in foods for treatment of various disease in livestock (see summary of invention, in particular).

The claimed invention in claim 1 differs from the teachings of the reference only in that the colony-forming immunogen is lactic acid producing immunogen.

The claimed invention in claims 2 and 4 differs from the teachings of the reference only in that the colony-forming immunogen is from the class of *Streptococcus bovis*.

The '555 patent teaches microorganism such as *Streptococcus bovis* is an important lactic acid bacterium in the rumen of livestock, which contributes to the development of lactic acidosis (see entire document, col. 1, lines 15-30, col. 3, lines 12-20, in particular). The '555 patent teaches the risk of lactic acidosis can be reduced by immunization against S. bovis to produce antibody that binds specifically to S. bovis (see claims of '555, in particular). The '555 patent further teaches the immunogen is SB antigen from *Streptococcus bovis* by culturing the bacterium in RSY-II medium for 6 to 10 h at 38.5 C, the bacterial cells suspension was used as SB antigen for the reference method (see col. 6, lines 47-61, in particular).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to substitute the immunogen such as the *E coli* as taught by the '895 patent for the lactic acid producing colony-forming immunogen such as *Streptococcus bovis* or SB antigen from *Streptococcus bovis* as taught by the '555 patent. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because *Streptococcus bovis* is an important lactic acid bacterium in the rumen of livestock, which contributes to the development of lactic acidosis and the risk of lactic acidosis can be reduced by antibody that binds specifically to *S. bovis* as taught by the '555 patent (see abstract, in

particular). The '895 patent teaches antibody containing egg powder from eggs of immunized hen against the bacterium which induces the disease is useful as additives in foods for treatment of various disease in livestock (see summary of invention, in particular). The step of drying of antibody containing contents alone or coating the dry feed carrier with the antibody containing contents of the eggs for uniformly distribution of the antibody prior to supplying the antibody containing content in the food or water is an obvious variation of the reference teachings since the '895 patent teaches drying the separated egg antibody from the shells by spray drying or lyophilizing to form powder product to be used as food additive for livestock (See column 6, line 24-25, in particular).

20. Claims 5-7, 10-12, 22-24, 27-29, 38-39, and 41-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (Jan 1992; PTO 1449) in view of US Pat No 6,287,555 B1 (filed May 13, 1998; PTO 892) as applied to claims 1-4, 8-9, 18-21 and 25-26, 36-37, and 40 mentioned above and further in view of and US Pat No 4,748,018 (May 31, 1988; PTO 1449), US Pat No. 3,878,298 (April 15, 1975; PTO 892) and US Pat No. 4,166,867 (Sept 1979, PTO 892).

The combined teachings of the '895 patent and the '555 patent have been discussed supra.

The claimed invention in claims 5 and 10 differs from the references only in that the method includes providing a dry feed carrier material, said drying the separated antibody containing contents of said eggs is achieved by coating dry feed carrier material with the antibody-containing contents of said eggs.

The claimed invention in claims 6 and 11 differs from the references only in that the method includes providing a dry feed carrier material, said drying the separated antibody containing contents of said eggs is achieved by coating dry feed carrier material with the antibody-containing contents of said eggs wherein the dry feed carrier is selected from the group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

The claimed invention in claims 7, 12 and 41 differs from the references only in that the method includes mixing the antibody-containing contents of the eggs with a liquid extender.

The claimed invention in claims 22 and 28 differs from the references only in that the microbial adherence inhibitor includes the dry feed carrier selected from the group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

The claimed invention in claims 23, 27, and 29 differs from the references only in that the microbial adherence inhibitor includes a liquid extender mixed with the antibody-containing contents of the eggs.

The claimed invention in claim 24 differs from the references only in that the microbial adherence inhibitor includes a liquid extender wherein the liquid extender is liquid molasses.

The '018 patent teaches avian antibody can be administered to a mammalian subject either directly as is, or is combined with a conventional pharmaceutically acceptable liquid or solid carrier (see col. 6, lines 60-66, in particular). The dehydrated egg antibody (dried egg antibody) can be used in the form of premixed food products or can be mixed in the feeding stage (see col. 9, lines 4-8, in particular).

The '298 patent teaches molasses are useful as feed additive in liquid feed formulations and molasses are widely used in feed mixing plants or growing farms (see col. 2, lines 27-62, in particular). The '298 patent further teaches various carriers such as soy bean meal, corn, cotton seed hulls, oats, barley for ruminant animals (see col. 4, lines 22-47, in particular). The supplemental animal feeds may contain cotton seed hulls that contain cellulosic roughage (see col. 4, lines 40-47, in particular).

The '867 patent teaches a method of making a high performance palatable horse feed comprising soybean hulls, rice hulls cottonseed hulls which provide the fibrous material and cereal grain such as corn and distilled dried grains provide the carbonaceous materials along with nutritional supplement (See column 3, lines 24-26, column 3, lines 10-18, claims of '867, in particular) while beet pulp provides high energy values (See column 2, line 12-13, in particular). The '867 patent teaches soybean hulls, rice hulls and cottonseed hulls provide the fibrous material as animal feed in order to provide adequate structural strength or integrity to the final feed pellets and also to effect stool normality (See column 3, lines 14-16, in particular).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to mix the dry feed carrier such as soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp as taught by the '867 patent or the '298 patent or the liquid extender (carrier) such as molasses as taught by the '298 with the appropriate egg antibody that is specific for colony-forming lactic acid producing *Streptococcus bovis* as taught by the '555 patent and the '895 patent. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because the '018 patent teaches avian antibody can be administered to a mammalian subject either directly as is, or is combined with a conventional pharmaceutically acceptable liquid or solid carrier (see col. 6, lines 60-66, in particular). The '298 patent teaches liquid carrier such as molasses are useful as feed additive in liquid feed formulations and molasses are widely used in feed mixing plants or growing farms (see col. 2, lines 27-62, in particular) and various carriers such as soy bean meal, corn, cotton seed hulls, oats, barley are widely use as a carrier for ruminant animals (see col. 4, lines 22-47, in particular). The supplemental animal feeds may contain cotton seed hulls that contain cellulosic roughage (see col. 4, lines 40-47, in particular). The '867 patent teaches the carrier material such as soybean hulls, rice hulls and cottonseed hulls provide the fibrous material and provide adequate structural strength or integrity to the final feed pellets to effect stool normality (See column 3, lines 14-16, in particular). The '878 patent teaches hyperimmunized spray-dried egg powder is useful for mixing with any animal feed or sprayed directly to coat the food pellets to maintaining antibody titers (See column 9, lines 37-46). The '555 patent teaches *Streptococcus bovis* is an important lactic acid bacterium in the rumen of livestock, which contributes to the development of lactic acidosis and the risk of lactic acidosis can be reduced by antibody that binds specifically to *S. bovis* (see abstract, in particular). The '895 patent teaches antibody containing egg powder from eggs of immunized hen against the specific bacterium which induces the disease is useful as additives in foods for treatment of various disease in livestock (see summary of invention, in particular). It is within the purview of one ordinary skill in the art to distribute the dried egg antibody product uniformly throughout animal feed or water as food additive or distributing the resulting egg mixture antibody directly without drying first by coating the animal feed uniformaly with the egg antibody containing content or water as food additive as taught by the '018 patent or '895 patent. Claims 36 and 40 are obvious variation of the references teachings.

21. No claim is allowed.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone

are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (571) 273-8300.

23. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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